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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,194	02/02/2004	Douglas Hovey	029318-1001	3657
31049 7590 01/10/2008 ELAN DRUG DELIVERY, INC. C/O FOLEY & LARDNER LLP 3000 K STREET, N.W. SUITE 500 WASHINGTON, DC 20007-5109			EXAMINER GEORGE, KONATA M	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 01/10/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/768,194

Applicant(s)

HOVEY ET AL.

Examiner

Konata M. George

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17,19-24,27-44,47-61,64-67 and 69-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17,19-24,27-44,47-61,64-67 and 69-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/25/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 are pending in this application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on October 31, 2007 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Restriction Requirement

Applicant's election without traverse of Group II, claims 17 and 19-81 in the reply filed on October 25, 2007 is acknowledged.

Action Summary

The examiner acknowledges the cancellation of claims 1-16, 25, 26, 45, 46, 62, 63, 68 and 82-99. Therefore, any and all objections and/or rejections directed to them are hereby withdrawn.

Claim Objections

Claims 36, 57 and 79 contain a comma after "and" which is not necessary. Please remove the comma.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33, 54 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants in the claims recite the phrase "derivatives". Webster's Dictionary defines a derivative as "a substance derived from, or of such composition and properties, that it may be considered as derived from, another substance by chemical change, esp. by the substitution of one or more elements or radicals". Based on this definition it is unclear what the derivative is.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karlsson et al. (US 2002/0065256 A1).

Applicants claim a fluticasone composition comprising particles of fluticasone having a particles size of less than 900 nm and at least one surface stabilizer.

Determination of the scope and content of the prior art
(MPEP §2141.01)

Karlsson et al. disclose a process for sterilization of a powdered form of a glucocorticosteroid wherein the glucocorticosteroids are used in the treatment of allergic and/or inflammatory conditions of the nose or lungs (abstract). ¶ [0016] teach examples of the glucocorticosteroid used in the composition i.e. fluticasone (e.g. as propionate). ¶ [0017] teach the particle size as less than 10 microns. ¶ [0031] teach the use of the composition. ¶ [0033] teaches the use of pharmaceutically acceptable additives. ¶ [0035] teach suitable surfactants that can be employed in the composition, mention being made to Tyloxapol™ and polyoxyethylene alkyl ethers. ¶ [0036] teach the concentration of the surfactant at about 0.002 to 2% w/w. ¶ [0042] teach the percentage of particles having a specific particle size. ¶ [0044] teach that a suspension containing the active agent and additional ingredients can be produced by sterile filtration. The several examples teach the active agent in concentrations as claimed by applicant.

***Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)***

Karlsson et al. do not teach specific examples using fluticasone as claimed by applicant.

***Finding of prima facie obviousness Rational and Motivation
(MPEP §2142-2143)***

It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the cited glucocorticosteroids in the instant invention. As paragraph [0016] teaches examples of glucocorticosteroids one of ordinary skill could substitute any one of the glucocorticosteroids listed (i.e. fluticasone) to achieve the same desired results of treating allergic and/or inflammatory condition of the nose or lungs (e.g. chronic obstructive pulmonary disease, asthma, etc.). Applicant has amended the claims to recite that the particles are small enough to pass through a 0.2 micron filter. Although the prior art does not teach exact size of the particle, it is the position of the examiner that since the particle size can be less than 1 micron ¶ [0017] the prior art reads on the claimed invention. Applicant would need to show why their particle size is preferred over that of the prior art.

Conclusion

Claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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